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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,384	10/13/2000	Timothy G. Dinan	99,829-A	7338

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 08/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/687,384	DINAN ET AL.
	Examiner	Art Unit
	Donna Jagoe	1614

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 July 2005 has been entered.

The amendment filed 6 July 2005 has been received and entered. Claim1 has been amended. ***Claims 1 and 3-7 are pending in this application.***

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buzas et al. RO 92436 in view of Santus et al. U.S. Patent No 5,883,115 A.

The claims are drawn treatment of gastrointestinal disease comprising administering a composition consisting essentially of an effective amount of S(-) pindolol or a salt thereof to a subject in need thereof. Dependent claims are drawn to a rapid release dosage form and a slow release dosage form.

Buzas et al. teach a composition comprising a carbonic anhydrase inhibitor and a beta-blocker such as pindolol (see abstract) to treat gastritis (an inflammation of the gastric mucosa), gastro-duodenitis and gastro-duodenal ulcers.

It does not teach S (-) pindolol.

Santus et al. teach that S(-) pindolol is the most active eutomer (enantiomer) (see column 2, lines 47-65 and see column 6, table II), wherein it is recited that S(-) pindolol has a eudismic ratio of 200. A eudismic ratio of 1 indicates that the two

enantiomers have the same pharmacodynamic activity for any particular therapeutic purpose. Thus, eudismic ratios of greater than one indicate that the eutomer has a greater pharmacodynamic ratio than the distomer (inactive enantiomer).

Thus, it would have been made obvious to one of ordinary skill in art at the time it was made to employ the S(-) eutomer of pindolol motivated by the teaching of Santus et al. that the S(-) eutomer is the most active portion of racemic pindolol.

Regarding the rapid release formulation and the slow release formulation, it would have been obvious to treat an acute gastrointestinal attack with a rapid release agent motivated by the fact that a rapid release of the active agent would permit fast relief of acute pain associated with a gastrointestinal disorder. In a chronic gastrointestinal disease, it would have been obvious to administer S (-) pindolol in a slow release matrix motivated by the fact that a slow release matrix would release the agent slowly, thus alleviating a chronic condition. Claim 7 is drawn to treatment of nausea. Since nausea is a disorder associated with the irritation/inflammation of the gastrointestinal system, it would have been obvious to treat nausea since Buzas et al. teach that, *interalia*, pindolol reduces gastric secretions (page 5, lines 31-40). Thus reducing the gastric secretions (acid) would inhibit nausea.

The examiner has taken the following from the MPEP § 2111.03 [R-2] "the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a

clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If the applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USP 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)." It does not appear that the addition of the carbonic anhydrase inhibitor of the prior art would materially change the characteristics of the appellant's invention since both agents would treat gastrointestinal disease. See Buzas et al., table 3, page 8, where the activity of some beta-adrenergic blockers were tested on the production of hydrochloric acid and the activity of gastric mucosa in patients with duodenal ulcers. Further, **Pindolol was dosed alone** (no carbonic anhydrase inhibitor) **for 10 days at 3 mg per dose**. While the inhibition of gastric acid was not significant, the instant claims do not address dosage or percent inhibition of gastrointestinal diseases.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
Patent Examiner
Art Unit 1614

08/05/2005

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